REMARKS

Status of the Claims

Claims 1-24 are pending in the application. Claims 10-24 are withdrawn from consideration. Claims 1-9 are in this case and have been rejected. Claims 1 and 9 have been amended.

Applicant's election of Group l, claims 1-9, filed June 18, 2009 was acknowledged and entered. Claims 10-24 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being claims drawn to a non-elected invention.

Information Disclosure Statement

The Examiner avers that the information disclosure statement filed June 14, 2006 failed to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because pages of references submitted were incomplete, that the IDS had been placed in the application file, but the information referred to therein has not been considered by the Examiner as to the merits, and that Applicant was advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a). In this case, the Examiner avers that Novaretti et al., Byrne et al., and Luhong et al. had unintentionally been submitted with alternating pages missing. Pages 312 and 314 are missing for Novaretti et al. Page 194 were missing for Byrne et al. Pages 36 and 38 were missing for Luhong et al..

Applicants have herewith respectfully submitted a Corrected Information Disclosure Statement listing and containing the above complete documents, along with the correct recitation of the EP010488**1**, which had been mis-typed as EP010480**1** in the

original IDS, along with a Supplemental IDS to include other art cited in the specification not previously submitted.

Examiner's Claim Rejections – 35 USC §112

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner avers that Claim 1, preamble is ambiguous in reciting, "A method for reducing time to result in immunohematology assay" because it is unclear what is encompassed in the term "result" as recited in the claim.

Further, the Examiner avers that in claim 1, step a) the abbreviation "RBCs" has not been fully defined, and that acronyms or abbreviations should be fully defined at least one time in a given set of claims.

Further, the Examiner avers that Claim 1, step a) is indefinite in reciting; "continuous agitation" because the term "continuous" is a subjective and relative term that lacks a comparative basis for defining its metes and bounds. See also claims 3 and 4.

Further, the Examiner avers Claim 1, step b) lacks clear antecedent in reciting, "the sample" because it is unclear as to whether the recitation refers back to "a sample" in step a) or "a sample incubated or mixed with antigen positive RBCs" in step a).

Further, the Examiner avers Claim 1, steps a) and b) are also ambiguous in reciting, centrifuging the sample..." because step a) fails to specifically define how the sample and the antigen positive RBCs are contained for continuous agitation by an agitation block and subsequently caused to be centrifuged in step b). Should the sample mixture be continuously agitated in a microtube and then poured into a column, i.e. another microtube, having disposed therein the anti-IgG matrix?

Further, the Examiner avers Claim 1, step c) is also vague and indefinite in

reciting, "reading the result" because it is unclear what is encompassed in the recitation of "result" used in the claim and inquires whether the term "result" means "a signal" or "agglutination degree" and to kindly clarify.

The Examiner avers Claim 9 is indefinite in reciting, "wherein the low ionic strength diluent is less than about 0.03M" because it is unclear how the diluent is a parameter, and inquires whether the Applicant intends, "wherein the low ionic strength diluent is ____"; or alternatively "wherein the diluent has a low ionic strength of less than about 0.03M?"

Applicants' Amendments and Arguments – 35 USC §112

The Examiner avers the term "time to result" in claim 1 is ambiguous as it is unclear what is encompassed in the term "result" as recited in the claim. Applicants point out that the term is disclosed and described in the specification at page 7, lines 26-29 wherein it is stated that "The instant invention is a method to reduce time to result in blood bank immunohematologic testing for tests that use incubation of the antibody and the red cell antigen." Further, at page 13, line 28 – page 14, line 5 it is clearly stated "The manipulation or combination of any of these variables of antigen-antibody reactions in test systems can reduce the time to result in blood bank testing. The instant invention is directed to reduction in incubation time required by use of continuous agitation while incubating." It is clear from this passage that "time to result" and in particular "reducing" time to result as stated in the preamble to claim 1 means reducing the time needed for incubation of the antigen red blood cells with the patient sample which may contain corresponding antibodies. Further, see page 21, Example 2 Part A, wherein incubation with agitation is results in a time of 4 minutes to reach maximum titer. Compare Example 2 Part B, Incubation with no Agitation, wherein time to reach maximum titer is 10 minutes. Based on these measured times to maximum titer, Applicants show that continuous agitation decreases the time to a reliable result.

In order to advance prosecution Applicants have amended claim 1 to recite that the result is "in the form of agglutination". Support for this amendment can be found in

the instant specification as filed in particular at page 6, lines 26-30 and at page 24, line 10.

Further, the Examiner avers that in claim 1, step a) the abbreviation "RBCs" has not been fully defined, and that acronyms or abbreviations should be fully defined at least one time in a given set of claims. Applicants have amended claim 1 to insert "red blood cells" before use of the abbreviation "RBCs". Support for this amendment can be found in the specification as filed at page 2, line 21.

Further, the Examiner avers that Claim 1, step a) is indefinite in reciting; "continuous agitation" because the term "continuous" is a subjective and relative term that lacks a comparative basis for defining its metes and bounds, also referencing claims 3 and 4.

The specification as filed, in particular at page 17, lines 16 - page 18, line 5, provides a detailed description of continuous agitation. See especially page 17, lines 29-34. The specification makes clear that agitation is carried out for the duration of the incubation. Applicants have amended claim 1 to recite the agitation is carried out for from 2 minutes to 15 minutes, which clarifies the duration of the agitation ("continuous") as linked to the incubation. The agitation allows for a shortened incubation time as measured by time needed to reach maximum titer. At 37°C, time to result was 4 minutes with agitation, compared to 10 minutes without agitation. At room temperature, time to result was 15 minutes with agitation, compared to 20 minutes without agitation. See Example 2 Parts A-D for this comparative data.

The Examiner avers Claim 1, step b) lacks clear antecedent in reciting, "the sample" because it is unclear as to whether the recitation refers back to "a sample" in step a) or "a sample incubated or mixed with antigen positive RBCs" in step a). Applicants have amended claim 1 step b) to delete reference to "a sample" and now recite "centrifuging the product of the admixture in step (a)".

The Examiner avers Claim 1, steps a) and b) are also ambiguous in reciting "centrifuging the sample..." because step a) fails to specifically define how the sample and the antigen positive RBCs are contained for continuous agitation by an agitation block and subsequently caused to be centrifuged in step b). The Examiner inquires whether the sample mixture should be continuously agitated in a microtube and then poured into a column, i.e. another microtube, having disposed therein the anti-IgG matrix.

Applicants draw the Examiner's attention to the instant specification at page 11, lines 23-33. In particular steps (a) and (b) set forth therein state (a) incubating a sample with antigen positive RBCs at 37° C with continuous agitation and (b) centrifuging the sample in an anti-IgG matrix (the Anti-IgG as either supplied within the matrix or added as a reagent) for 10 minutes". This passage clearly discloses that either method can be used.

Further, the Examiner avers Claim 1, step c) is also vague and indefinite in reciting, "reading the result" because it is unclear what is encompassed in the recitation of "result" used in the claim; for instance, whether the term result means "a signal" or "agglutination degree", and requests clarification.

In the immunohematology agglutination assay art, the "result" is the determination, whether visual or optical, of an antigen-antibody reaction having taken place, which is demonstrated by the formation of a visually determinable agglutination between the antigen and antibody. See page 3, line 33 to page 4, line 6. Where a tube containing a matrix containing anti-IgG is employed, after centrifugation the "result" is read as a scalable or graded (weak → strong) positive result if there are few or no cells at the bottom of the reaction vessel. Such agglutinates form a layer above the matrix. The matrix will have prevented some or all of the agglutinated cells from passing through to the bottom of the reaction vessel. In this latter case, the "result" will be read as positive. However, in a weak reaction some unagglutinated cells will pass through the matrix to reside on the bottom of the reaction vessel. See specification at page 6, line 14 to page 7, line 24.

The Examiner avers Claim 9 is indefinite in reciting, "wherein the low ionic strength diluent is less than about 0.03M" because it is unclear how the diluent is a parameter, and inquires whether the Applicant intends "wherein the low ionic strength diluent is ___"; or alternatively "wherein the diluent has a low ionic strength of less than about 0.03M?"

Applicants acknowledge these comments and have amended claim 9 to recite that the diluent has a low ionic strength of less than about 0.03 M.

Given the above amendments and remarks, Applicants respectfully submit the rejections under 35 USC 112 have hereby been overcome and should be withdrawn.

Claim Rejections – 35 USC §102

Claims 1, 2 and 4-8 are rejected under 35 U.S.C. 102(a) as being inherently (sic) by Novaretti et al. (Comparison of conventional tube test with diamed gel microcolumn assay for anti--D titration, Clin. Lab. Haem. 25: 311-315 (2003)) in light of Chachowski et al. (US Patent 5,552,064).

The Examiner avers that Novaretti et al. provide a comparison between conventional tube test and gel microcolumn assay in order to detect red blood cell (RBC) alloantibodies including anti-D titers in RhD sensitized patients (Abstract), and that for tube testing, a serum sample is obtained from an anti-D alloimmunized patient and then incubated with red blood cells, i.e. RBCs (red cell suspension) which are RhD antigen positive for 60 minutes at 37 °C, that the RBCs are admixed in a diluent solution having a low ionic strength and that thereafter, the mixture is combined with anti-IgG matrix (monoclonal rabbit antihuman IgG) and then centrifuged for 15 seconds. The Examiner avers that result in the form of agglutination or hemolysis is examined and read for graded positive result from 1+ to 4+, and for gel microcolumn assay method, a serum sample is obtained from an anti-D alloimmunized patient and then incubated with RhD antigen positive RBCs admixed in a diluent solution having a low ionic strength for 15 minutes at 37 °C, that the RBCs are admixed in a diluent solution having a low ionic strength and that thereafter, the mixture is combined with anti-IgG matrix and then

centrifuged for 10 minutes. The Examiner avers the result in the form of agglutination or hemolysis is examined and read for graded positive result from 1 + to 4+.

The Examiner avers that the anti-IgG matrix is disposed in a microtube, and that, accordingly, Novaretti et al. provide that the gel microcolumn assay method has reduced processing time for immunohematology agglutination assays (p. 312, col. 1-2), and that Novaretti et al. and other literature also provide that the gel microcolumn assay requires small volumes of blood sample, is relatively stable at room temperature with standardized reaction endpoints, making it theoretically an ideal method for prenatal antibody titration studies (citing p. 313, col. 2).

While the Examiner states that Novaretti et al. is silent in teaching that the sample is mixed with the antigen positive RBCs, she avers that Chachowski et al. teach that mixing antigen positive red blood cells with a reagent comprising their corresponding antibodies, i.e. by manual agitation, is required, well known in prior art, conventional, and a standard laboratory practice so as to allow cell antigen/antibody reactions to take place prior to centrifugation (col. 2, lines 29-41).

The Examiner further avers that Chachowski et al. also disclose a method and device for detecting the presence of blood group antibodies which utilize a matrix of non-compressible microparticles, and that the method has application in serology and immunohematology (col. 1, lines 11-14). The Examiner avers the matrix provides for superior performance in allowing movement of non-agglutinated reactants, especially red blood cells (Abstract), and in practice, a serum sample is contacted, mixed, and incubated with antigen positive RBCs (Kell, Duffy, Kidd antigen), the cell mixture is centrifuged in a column containing anti-IgG matrix disposed in a microtube (col. 8, lines 12-26; col. 9, lines 27-34). The anti-IgG matrix comprises glass beads (non-compressible microparticles) (col. 3, lines 45-53; col. 6, lines 1-13). The Examiner avers Chachowski et al. provide that gel matrices are also known and used in the art (col. 2, line 65 to col. 3. line 4), and that the microtube is read and observed for agglutination or non-agglutination (col. 2, lines 6-20).

The Examiner concludes that accordingly, the teaching of Novaretti et al. in light of Chachowski et al. reads on the claimed invention.

The Examiner continues that in as far as the recitation of "continuous" in reference to the recitation of "agitation" or "mixing", it is understood that mixing by shaking a test tube as shown by Chachowski et al. is deemed to be "continuous" in nature in order to effect mixing of the reagent with the sample, and absent a clear definition of what parameters encompass the term "continuous" it is proper for purposes of this anticipatory rejection to interpret "mixing" or "shaking" as "continuous agitation" because unpatented claims are given the broadest reasonable interpretation of the term consistent with the specification.

Claims 1, 2, and 4-8 were rejected under 35 U.S.C. 102(b) as being inherently (sic) by Byrne et al. (A Comparison of two column agglutination technologies for routine antibody screening using the indirect antiglobulin technique, British Journal of Biomedical Science 53: 193-195 (1996)) in light of Chachowski et al. (US Patent 5,552,064).

The Examiner avers that Byrne et al. provide a comparison between two commercial column agglutination technologies for routine antibody screening using indirect antiglobulin technique; that the DiaMed system uses Sephadex gel and the Biovue system uses minute glass beads, and that both systems have incorporated into their gel or glass bead matrices, anti-IgG globulin antibodies (AHG) so as to trap agglutinates and allow unagglutinated RBCs to pass through the matrix into the base of the microtube (Abstract; p. 193, col. 1). The Examiner avers that both systems were tested with the RBCs admixed with a low ionic strength diluent, i.e. LISS (p. 193, col. 2), and for DiaMed microtyping system, heparinized plasma (serum) samples are obtained from patients and then incubated with antigen positive RBCs for 20 minutes at 37 °C, and thereafter, the mixture is combined with anti-IgG (AHG) matrix in Sephadex gel and then centrifuged for 10 minutes, and the result in the form of agglutination is examined and read for graded positive result (p. 194, column 1). The Examiner avers that for BioVue system, heparinized plasma (serum) samples are obtained from patients

and then incubated with antigen positive RBCs for 20 minutes at 37 °C, and that thereafter, the mixture is combined with anti-IgG matrix in minute glass beads incorporated into a microtubule and then centrifuged for 5 minutes via biphasic spin cycle, and the result in the form of agglutination is examined and read for graded positive result (p. 194, column 1). The Examiner avers that Byrne et al. provide that both procedures gave rapid stable results (p. 194, col. 2). Byrne et al. also teach that agitating (rigorous handling) of the test mixtures is not a problem with both column agglutination technologies (p. 195, col 1).

The Examiner continues that indeed, Byrne et al. teach that agitating (rigorous handling) of the test mixtures comprising serum samples and antigen positive RBCs, is not a problem with both gel and glass bead matrices in column agglutination technologies, that Chachowski et al. also 'teach that mixing antigen positive red blood cells with a reagent comprising their corresponding antibodies, i.e. by manual agitation, is required, well known in prior art, conventional, and a standard laboratory practice so as to allow cell antigen/antibody reactions to take place prior to centrifugation (col. 2, lines 29-41), and that accordingly, the teaching of Byrne et al. in light of Chachowski et al. reads on the claimed invention.

The Examiner continues that in as far as the recitation of "continuous" in reference to the recitation of “agitation" or "mixing", it is understood that mixing by shaking a test tube as shown by Byrne et al. and Chachowski et al. is deemed to be "continuous" in nature in order to effect mixing of the reagent with the sample, and that absent a clear definition of what parameters encompass the term "continuous", it is proper for purposes of this anticipatory rejection to interpret "mixing" or "shaking" as "continuous agitation" because unpatented claims are given the broadest reasonable interpretation of the term consistent with the specification.

Applicants' Amendment and Argument – 35 USC §102

Novaretti et al., and Chachowski et al.

Applicants have considered the Examiner's rejection and strongly disagree. Contrary to the Examiner's presumption, Chachowski et al. does not disclose agitation during incubation. The Examiner cites Chachowski at col. 2 lines 29-41 for the proposition that Chachowski teaches that mixing antigen positive red blood cells with a reagent comprising their corresponding antibodies , i.e. by "manual agitation", is required, so as to allow cell antigen/antibody reactions to take place prior to centrifugation, that in fact that such agitation is well known in prior art, as a conventional, and a standard laboratory practice (col. 2, lines 29-41). Applicants respectfully traverse the rejection and point out that this is an incorrect reading of Chachowski et al.

At the passage in Chachowski et al. cited by the Examiner, there is a discussion of Landsteiner's agglutination method of the early 1900's. In this method, into a test tube is added patient serum (containing antigen) and a blood group antibody. The test tube is mixed and centrifuged. At that point, reports Chachowski, the test tube is "manually shaken", the stated purpose of which (see col. 2 line37-38) is *to dislodge the clumped cells at the bottom of the test tube to determine to what extent there may be true agglutinates*. The teaching is clear that the "manual shaking" at this point in the Landsteiner method has nothing whatsoever to do with incubation of the antigen-antibody with agitation. That mixing has already occurred by the time the :manual shaking" has been performed.

The Examiner's assertion that Chachowski et al. teaches "mixing by shaking a test tube . . . is understood to be "continuous" in nature in order to effect mixing of the reagent with the sample", is inaccurate. As stated above, nothing in Chachowski teaches or suggests Applicants' invention of incubation with continuous agitation, because the "mixing by shaking a test tube" discussed by Chachowski et al. is not done during incubation, but is done after incubation and centrifugation, and solely for the purpose of

an expedient to the visual observation of whether there was an immunological reaction; that is, whether the cells dislodged by such shaking are truly agglutinates, and to what extent (col. 2 lines 36-41). Applicants therefore respectfully submit that nothing in Novaretti et al. combined with Chachowski et al. anticipate Applicants' claims and that this rejection should be withdrawn.

Byrne et al.

Applicants have considered the Examiner's rejection and strongly traverse the rejection.

It is not in dispute that Byrne et al. test the two immunohematology systems of DiaMed® and BioVue®, and that, per the Examiner, "both systems have incorporated into their gel or glass bead matrices, anti-IgG globulin antibodies (AHG) so as to trap agglutinates and allow unagglutinated RBCs to pass through the matrix into the base of the microtube". The Examiner then goes on to aver that Byrne et al. "teach that agitating (rigorous handling) of the test mixtures is not a problem with both column agglutination technologies (page 195, col 1), and that "Byrne in light of Chachowski reads on the claimed invention."

Chachowski et al. has been discussed supra. Nothing in the disclosure of Landsteiner methods by Chachowski refers to agitation of the test mixture during incubation that would reduce time to result. In fact, the method is to the contrary, in that Chachowski is reporting on Landsteiner's agitation of the test tube *after* incubation and centrifugation, to dislodge cells to evaluate the result.

As to Byrne et al., there is nothing therein, including the passage cited by the Examiner, that discloses any agitation of the tube reactants *during incubation*. Byrne et al. relates to "possible over-vigorous handling of *the completed test* prior to reading in the tube" (emphasis added). Byrne et al. is conjecturing whether disruption of the gel bed *after the test is complete* might lead to an incorrect result. Such handling had been previously reported to produce false negative results. It is important to distinguish that Byrne et al. is reporting on potential agitation of the *completed test* and has nothing

whatsoever to do with use of agitation during the incubation. For this reason, Applicants respectfully submit that nothing in Byrne et al., when combined with Chachowski et al. result in Applicants' claimed invention, since nothing in either document discloses agitation during incubation. Therefore, it is Applicants' request that this rejection be withdrawn and the amended claims be allowed.

Claim Rejections – 35 USC §103

The Examiner states that this application currently names joint inventors and that in considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C FR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Novaretti et al. (Clin. Lab. Haem. 25: 311-315 (2003)) or Byrne et al. (British Journal of Biomedical Science 53: 193-195 (1996)) in light of Chachowski et al. (US Patent 5,552.064).

Novaretti et al., Byrne et al. and Chachowski et al. are discussed supra.

The Examiner states that Novaretti et al., Byrne et al., and Chachowski et al. differ from the instant invention in failing to teach that the low ionic strength diluents has an ionic strength of less than about 0.03M. The Examiner maintains that diluent parameters such as low ionic strength of 0.03M in diluent solvents for incorporation into reagents in immunohematology assays are all result effective variables which the prior art references have shown may be altered in order to achieve optimum results. It has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable. "Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable

ranges by routine experimentation." Application of Aller, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation." Id. at 458, 105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Application of Boesch, 617 F.2d 272, 276, 205 USPQ 215, 218-219 (C.C.P.A. 1980). Since Applicant has not disclosed that the specific limitations recited in instant claim 9 is for any particular purpose or solve any stated problem and the prior art teaches use of low ionic strength diluents in compatibility testing, and that parameters may vary according to the sample being analyzed and various matrices being used; absent unexpected results, it would have been obvious for one of ordinary skill to discover the optimum workable range for low ionic strength diluents used in irnmunohematology methods disclosed by the prior art by normal optimization procedures.

Applicants' Amendment and Argument – 35 USC §103

Applicants traverse the rejection of claim 9 for the following reasons.

The Examiner rejects the claim "Since Applicant has not disclosed that the specific limitations recited in instant claim 9 is for any particular purpose or solve any stated problem". The Examiner further avers that the prior art teaches use of a low ionic strength diluent.

Applicants respectfully disagree.

Claim 9 is dependent on claim 1.

With regard to disclosing the particular purpose of Applicants' use of a low ionic strength diluent, see the specification as filed at page 9, line 32 to page 10, line 5. That passage specifically cites Low and Messiter, Vox Sang 1974, Vol. 26, p. 53 for the proposition that use of a buffer of about 0.03M is most useful. Low and Messiter disclose these advantages in their Abstract (at the second paragraph), and at Table 1 (that 0.03M salt solutions were used throughout), as well as page 56 (first sentence of last

paragraph), and at Discussion (recitating benefit of using a low ionic strength solution is well known and routine).

Other support is found in the specification as filed at page 12, lines 8-13, page 13, lines 1-3, page 14, lines 17-21, and page 15, lines 22-30, page 16, lines 8-23 wherein it is specifically stated that:

> " With the introduction of low ionic strength solutions in immunohematology, the uptake of antibody by red blood cells occurred more rapidly than observed in a normal ionic strength solution. Such low ionic strength solutions include those as disclosed by Low and Messiter, ibid. and MTS Diluent 2TM (Micro Typing Systems, Inc., Pompano Beach, FL). In an even lower ionic strength system such as that contemplated in the present invention, the incubation times can be reduced in the performance of indirect antiglobulin testing to 10-15 minutes.
>
> Consequently, an agitation-incubation device combined with a low ionic strength red blood cell diluent maximizes antibody uptake on red cells and can significantly reduce the incubation time in indirect antiglobulin testing procedures. Such low ionic strength solution is typically less than 0.03M concentration."

Claim 9 is dependent on claim 1 which is directed to use of agitation during incubation. None of the art cited suggests an agitation method, much less discloses the advantage of employing a low ionic strength diluent together with agitation during incubation. Therefore, Applicants respectfully request that this rejection should be withdrawn and amended claim 9 proceed to allowance.

Applicants respectfully submit that in light of the amendments to the claims and the argument presented herein, the claims are in condition for allowance, which is now earnestly solicited. If any questions arise which can be disposed through interview, or if the Examiner has any further issue in order to prepare the claims for allowance, the Examiner is encouraged to contact Applicants' attorney at the telephone number listed below.

Please charge any fees due in connection with the filing of this response to Deposit Account No.10-0750/MTS5003USPCT/CKG in the name of Johnson & Johnson. The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Account No. 10-0750/MTS5003USPCT/CKG.

Respectfully submitted,

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